

K091593

Section 5 – 510(k) Summary

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Trade Name: AngioJet® Ultra DVX® Thrombectomy Set
AngioJet® Ultra Xpeedior® Thrombectomy Set

Classification: 870.5150 and 870.1210

Product Code: DXE and KRA

Predicate Device(s): The subject devices are equivalent to the following devices:

- K071342 and K090253 AngioJet Ultra Xpeedior Thrombectomy Set
- K072269 and K090253 AngioJet Ultra DVX Thrombectomy Set

Device Description: AngioJet Ultra DVX and Xpeedior Thrombectomy Sets are sterile, single use, disposable sets that include a Thrombectomy Catheter and Pump in one combined unit. The AngioJet Ultra DVX and Xpeedior Thrombectomy Sets are used with the AngioJet Ultra Console.

Intended Use: The AngioJet Ultra DVX and Xpeedior Thrombectomy Sets are intended for use with the AngioJet Ultra Console to break apart and remove thrombus from :

- * upper and lower extremity peripheral arteries $\geq 3.0\text{mm}$ in diameter,
- * upper extremity peripheral veins $\geq 3.0\text{mm}$ in diameter,
- * iliofemoral and lower extremity veins $\geq 3.0\text{mm}$ in diameter,
- * A-V access conduits $\geq 3.0\text{mm}$ in diameter and
- * for use with the AngioJet Ultra Power Pulse Kit for the control and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system.

Functional and Safety Testing: Representative samples of the device underwent mechanical bench testing to demonstrate safety and effectiveness and appropriate functional and performance characteristics.

Conclusion: MEDRAD Interventional / Possis considers the AngioJet Ultra DVX and Xpeedior Thrombectomy Sets to be substantially equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in functional design, materials, indications for use, and principles of operation.